III. 510(K) Summary

SUBMITTED BY:

MAY 10 2006

Globus Medical Inc.
303 Schell Lane
Phoenixville, PA 19460
(610) 415-9000
Contact: Kelly J. Baker

DEVICE NAME:

XPand Radiolucent Corpectomy Spacer

CLASSIFICATION:

Per CFR 21 §888.3060: Implant, fixation, spinal intervertebral body fixation orthosis devices. Class II. The Product Code is MQP. The Panel Code is 87.

PREDICATE DEVICES:

Globus XPand Corpectomy Spacer K050850, SE date May 26, 2005
Globus Sustain Radiolucent Spacer K040284, SE date March 23, 2004

DEVICE DESCRIPTION:

The XPand Radiolucent Corpectomy Spacer device is a vertebral body replacement device used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various heights and footprints to fit the anatomical needs of a wide variety of patients. Each spacer has an axial hole to allow grafting material to be packed inside of the spacer. Protrusions on the superior and inferior surfaces of each device will grip the endplates of the adjacent vertebrae to resist expulsion.

The XPand devices are made from radiolucent polymer, titanium alloy, and tantalum as specified in F2026, F136, F1295, and F560.

INTENDED USE:

The XPand Radiolucent Corpectomy Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The XPand Radiolucent Corpectomy Spacer is intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material.

The XPand Radiolucent Corpectomy Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

PERFORMANCE DATA:

Mechanical testing in accordance with the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004 is presented.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The XPand Radiolucent Corpectomy Spacer implants are similar to the predicate vertebral body replacement device, XPand Corpectomy Spacer (K050850), with respect to functional design, indications for use, principles of operation, and performance. The material is changed to a radiolucent polymer that is being used in other legally marketed devices within the same classification regulation for the same intended use as the XPand Radiolucent Corpectomy Spacer.

II. Indications for Use Statement

510(k) Number: K060665

Device Name: XPand Radiolucent Corpectomy Spacer

Indications:

The XPand Radiolucent Corpectomy Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The XPand Radiolucent Corpectomy Spacer is intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material.

The XPand Radiolucent Corpectomy Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR §801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

Globus Medical Incorporated
c/o Kelly Baker, Ph.D.
Project Manager, Regulatory Affairs
303 Schell Lane
Phoenixville, Pennsylvania 19460

Re: K060665
Trade Name: XPand Radiolucent Corpectomy Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: April 12, 2006
Received: April 13, 2006

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K060665

Device Name: XPand Radiolucent Corpectomy Spacer

Indications:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060665